REMARKS

Applicants have received and carefully reviewed the Office Action mailed January 13, 2005. Claims 206 and 208 are amended above, and claims 199 and 212 have been cancelled. Claims 192-198, 200-206, 208-211, and 213-217 remain pending. Reconsideration and reexamination of the claims are respectfully requested.

Applicants have cancelled claim 199, without prejudice, as claim 199 recited a structural element that is already recited in base claim 193.

In paragraph 2 of the Office Action, claim 206 was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,441,518 to Adams. Claim 206, as amended, recites:

> 206. A method of supplying energy for alleviating a cardiac dysfunction, the method comprising:
>
> implanting a device having a power source and an energy storage system into a patient;
>
> providing a lead system having one or more electrodes for the device, the lead system provided such that it is disposed internally to a patient without contacting the patient's heart;
>
> coupling the power source to the energy storage system;
>
> storing energy in the energy storage system; and
>
> discharging the energy from the energy storage system to the patient, the step of discharging the energy including using at least one electrode disposed in the lead system;
>
> wherein the step of discharging the energy uses only a first electrode that is part of the lead system and an electrode means for dispensing current to tissue disposed on the device itself, wherein the amount of energy discharged is selected to achieve a defibrillation function.

As amended, claim 206 recites only the use of a first electrode that is part of the lead system and an electrode means disposed on the device itself during the step of discharging the energy.

Adams suggests a number of differently placed electrodes including a superior vena cava (SVC) electrode, a right ventricular apex (RVA) electrode, an electrode placed on a canister (Can), and a subcutaneous patch electrode (Sub Q). Adams shows a "multiplexing" system for determining which of the several electrodes are used as cathodes and anodes during delivery of stimulus. Table II of Adams shows 38 configurations for delivering stimulus. Given 4 variables (SVC, RVA, Can, Sub Q) that can have one of three discrete values (-1, 0, 1), there are, mathematically, $3^4 = 81$ possible combinations. There must be a cathode and an anode in each valid therapy delivery combination, meaning some of those 81 mathematical possibilities are not

valid therapy delivery combinations. The following chart shows all such "valid" shock delivery combinations, including the number used by Adams for referring to those combinations disclosed by Adams:

#	SVC	RVA	Can	Sub Q	Adams #
1	-1	-1	-1	1	35
2	-1	-1	0	1	34
3	-1	-1	1	-1	33
4	-1	-1	1	0	12
5	-1	-1	1	1	32
6	-1	0	-1	1	
7	-1	0	0	1	38
8	-1	0	1	-1	37
9	-1	0	1	0	11
10	-1	0	1	1	36
11	-1	1	-1	-1	31
12	-1	1	-1	0	10
13	-1	1	-1	1	27
14	-1	1	0	-1	29
15	-1	1	0	0	9
16	-1	1	0	1	30
17	-1	1	1	-1	28
18	-1	1	1	0	8
19	-1	1	1	1	26
20	0	-1	-1	1	
21	0	-1	0	1	24
22	0	-1	1	-1	
23	0	-1	1	0	7
24	0	-1	1	1	25
25	0	0	-1	1	XXX
26	0	0	1	-1	YYY
27	0	1	-1	-1	
28	0	1	-1	0	6
29	0	1	-1	1	
30	0	1	0	-1	23
31	0	1	1	-1	
32	1	-1	-1	-1	21
33	1	-1	-1	0	5
34	1	-1	-1	1	19
35	1	-1	0	-1	20
36	1	-1	0	0	4
37	1	-1	0	1	18
38	1	-1	1	-1	
39	1	-1	1	0	3
40	1	-1	1	1	17

41	1	0	-1	-1	15
42	1	0	-1	0	2
43	1	0	-1	1	
44	1	0	0	-1	16
45	1	0	1	-1	
46	1	1	-1	-1	13
47	1	1	-1	0	1
48	1	1	-1	1	
49	1	1	0	-1	14
50	1	1	1	-1	

Note- Adams #22 is in error on the Adams Patent.

As noted, Adams suggests a combination, #22, that appears to contain a typographical error, as there is no anode in that combination.

Adams states:

> As shown in Table II, with the addition of a fourth electrode, the present invention realizes a geometric increase in the therapeutic countershock pathways available to the physician for programming the cardioverter/defibrillator. Table II only tabulates the therapeutic modalities for a four electrode system.

(Adams at column 9, lines 28-33). It appears, therefore, that the 13 out of 50 valid shocking combinations (combinations having both an anode and a cathode) not listed in Table II were not considered therapeutic modalities by Adams. In contrast, with only three electrodes, there are only 12 valid shocking configurations; all 12 such configurations are shown in Table I by Adams and are therefore considered therapeutic. The recited combination (noted on the table by the XXX and YYY) makes up two of the 13 valid shocking combinations that Adams apparently does not consider to be therapeutic.

In light of the above, Adams makes it quite clear that using only a canister electrode means in combination with a non-cardiac electrode, as recited, is not considered a therapeutic modality. Furthermore, Adams does not actually disclose a combination using only the recited electrodes set forth in claim 206 for stimulus delivery. Since actual disclosure is required under §102(b), a *prima facie* case under §102(b) is not made by reference to Adams. Although an obviousness rejection has not been made, as shown above, it appears that the recited combination is not obvious, either.

Applicants note that claim 195, which depends from claim 206, was rejected separately with citation to different references. However, the specifics of claims 195 and 206 were not discussed in the separate rejection, such that Applicants believe the intent was (or would have been) to include claim 195 in the Adams rejection. In light of the above, claim 206, along with dependent claim 195, is believed to be patentable over Adams.

In paragraph 3 of the Office Action, claims 208 and 212 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,148,230 to KenKnight.

Claim 208 has been amended to incorporate former claim 212, with an adjustment made to correct what could have been considered an ambiguity under §112. Specifically, the term "lead system" from former claim 212 has been changed to "lead assembly", and the phrasing regarding extending the lead assembly medially from the device has been modified to make the terminology consistent.

> 208. A method of supplying an electrical stimulus to a patient's heart comprising:
>
> providing a lead assembly including a first electrode implanted in a patient, the lead assembly provided such that it does not contact the patient's heart;
>
> providing a device including a battery and a means for storing energy, the device being coupled to the lead assembly;
>
> providing a second electrode implanted such that it does not contact the patient's heart;
>
> sensing far-field signals using a sensing electrode pair including the first electrode to monitor a portion of the patient's cardiac rhythm;
>
> determining whether the patient's cardiac rhythm requires electrical therapy; and, if so:
>
> supplying energy from the battery to the energy storage means; and
>
> discharging energy stored in the energy storage means to the patient using a stimulus electrode pair including the second electrode;
>
> wherein the second electrode is provided on a housing of the device; and
>
> wherein the step of providing the lead assembly includes extending the lead assembly medially from the device.

As amended, claim 208 recites both providing the lead assembly such that it does not contact the patient's heart and also extending the lead assembly medially from the device. KenKnight proposes the use of multiple lead assemblies including a lead assembly 20 that generally extends (anatomically) distally from the patient's shoulder as it goes away from the canister, as well as another lead assembly 10 that extends medially from the canister. However, the lead assembly

10 that extends medially from the canister is in contact with the patient's heart. The lead assembly 20 that is not in contact with the patient's heart extends distally from the canister, rather than medially.

Neither lead assembly satisfies the recitations of claim 208. Because claim 208 recites a lead assembly, rather than a complete system, one of the two lead assemblies 10, 20 would have to meet each claim element in order to anticipate the claim. As neither lead assembly 10, 20 does so, it is believed that claim 208 is patentable over the cited reference.

Claim 212 has been cancelled without prejudice, rendering that portion of the rejection moot.

In paragraph 5 of the Office Action, claims 192-199 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,411,547 to Causey, III in view of U.S. Patent No. 5,331,966 to Bennett et al. Claim 199 has been cancelled without prejudice.

Applicants note that claim 195 actually depends from claim 206. Claim 206 recites, in relevant part, a lead system provided such that it is disposed internally to a patient without contacting the patient's heart, a step of discharging the energy using a first electrode that is part of the lead system and a second electrode disposed on the device itself and that the amount of energy discharged is selected to achieve a defibrillation function. This combination is not addressed in the rejection, and it does not appear that this combination is shown by the cited references. It appears to Applicants, therefore, that the rejection is an oversight, but the oversight is moot as claim 195 is clearly patentable over the cited combination.

Independent claim 193 recites:

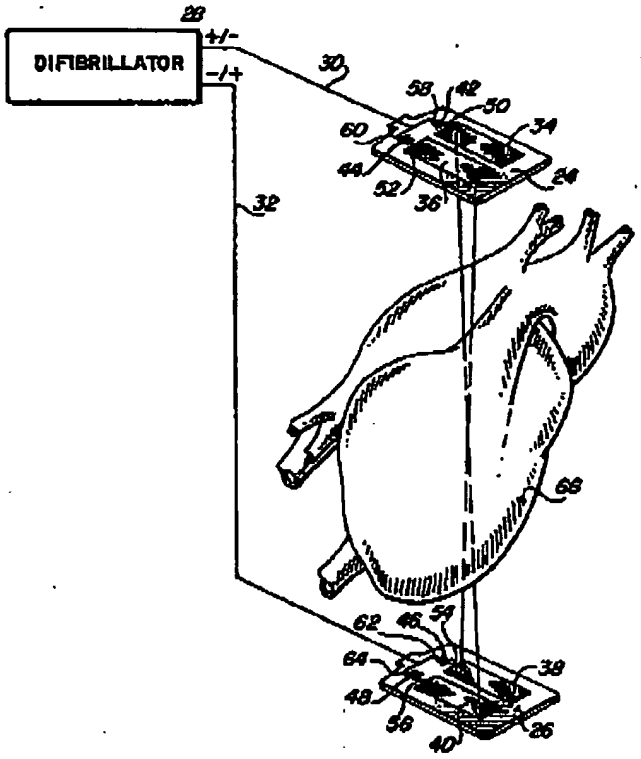
> 193. A method of supplying energy for alleviating a cardiac dysfunction, the method comprising:
>
> implanting a device having a power source and an energy storage system into a patient;
>
> providing a lead system having one or more electrodes, the lead system provided such that it is disposed internally to a patient without contacting the patient's heart;
>
> sensing an abnormality in the patient's cardiac rhythm using electrodes disposed internally to the patient but not contacting the patient's heart;
>
> coupling the power source to the energy storage system;
>
> storing energy in the energy storage system; and

discharging the energy from the energy storage system to the patient, the step of discharging the energy including using at least one electrode disposed in the lead system;

wherein the step of sensing an abnormality further includes determining whether the patient has an abnormally slow heart rate.

The underlined portions are the focus of the present remarks.

The figures shown in Causey, III are somewhat deceptive. Specifically, Figure 4 shows:



It may appear that the electrodes are not on the patient's heart. However, Figure 4 is inaccurate as to the positioning of the electrodes. For example, Causey, III state:

Various shocking electrode configurations are known. One implantable shocking electrode may be positioned within the right ventricle of right atrium of the heart, with the distal tip of the transvenous lead being used for pacing. The other implantable shocking electrode may be positioned either directly on the ventricular myocardium or subcutaneously positioned along the interior chest wall.

Other known implantable shocking electrode configurations used in conjunction with implantable defibrillators employ electrodes which are all in contact with the exterior surface of the human heart.

(Causey, III at column 1, lines 40-51). As explained throughout the Causey, III patent, the point of the patent is to illustrate how the patch electrodes operate, with current flow controlled via diodes placed as part of the patch electrodes. To that end, it appears Causey, III uses rather diagrammatic illustrations that, as shown by the above quotation, do not correspond to the physical placement of the electrodes.

Causey, III also states:

> The electrodes 34, 36, 38 and 40 can be used as conformal electrodes (in direct contact with the heart) or can be arranged near the surface of the heart 66 (illustrated in FIG. 1). The patch electrodes 34, 36, 38 and 40 can be suitably arranged in an anterior-anterior or anterior-posterior position.

(Causey, III at column 3, lines 48-53). It is believed that, in accordance with the earlier Causey, III statements, the description of "arranged near the surface of the heart" means an electrode that is epicardial, placed on the surface of the heart, but which is also non-conformal. One of the inventive aspects of Causey, III is that there are multiple separate electrodes on each patch electrode. If non-conformal, the lead assembly may only touch the heart over a limited area. Given that there are multiple electrodes on each lead assembly, this means that an electrode on a given lead assembly does not necessarily touch the heart. Applicants believe that this explains the "arranged near the surface of the heart" statement.

Claim 193 recites providing a lead system having one or more electrodes, the lead system provided such that it is disposed internally to a patient without contacting the patient's heart. With Causey, III, at least some portion of the lead system is in contact with the patient's heart. The recited lead system includes a shocking electrode as set forth in claim 193: "the step of discharging the energy including using at least one electrode disposed in the lead system". The question therefore is not whether a particular electrode touches the heart, but instead whether the lead system, which includes leads and one or more electrodes, touches the heart. Causey, III does not disclose such a device.

With respect to claims 192-194 and 196-198, Bennett et al. is cited primarily to show a system wherein sensing electrodes are positioned such that they do not contact the heart. Bennett et al. clearly show that the pacing leads touch the heart, as shown in Figure 1. The cited combination does not disclose or fairly suggest the combination of elements recited in claim 193.

Therefore, independent claim 193 and dependent claims 192, 194, and 196-198 are believed to be patentable over the cited combination.

In paragraph 6 of the Office Action, claim 200 was rejected under 35 U.S.C. §103(a) as being unpatentable over Causey, III in view of Bennett et al. and U.S. Patent No. 5,292,338 to Bardy. It is believed that the above discussion applies with equal force to claim 200. Indeed, the '338 patent to Bardy shows a defibrillator having leads extending into the heart of the patient as well. Claim 200 is believed to be in condition for allowance over the cited combination.

Applicants thank the Examiner for indicating allowance of claims 201-205, 209-211, and 213-217.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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